

WHAT IS CLAIMED IS:

1. A pharmaceutical formulation comprising
a biologically active agent and methionine, wherein
5 said formulation demonstrates improved stability, and
wherein said formulation does not contain human serum
albumin.

2. A formulation according to Claim 1
10 wherein said methionine is present in a concentration
of about 0.5mM-50mM.

3. A formulation according to Claim 2
wherein said active agent is selected from the group
15 consisting of peptides, small molecules, carbohydrates,
nucleic acids, lipids, proteins, and analogs thereof.

4. A formulation according to Claim 3
wherein said active ingredient is a protein.
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5. A formulation according to Claim 4
wherein said protein is erythropoietin (EPO).

6. A formulation according to Claim 5
25 wherein said EPO has an amino acid sequence as depicted
in SEQ ID NO:1.

7. A formulation according to Claim 6
further comprising a pH buffering agent which provides
30 a pH range of about 5 to about 7.

8. A formulation according to Claim 7
further comprising a stabilizing amount of a sorbitan
mono-9-octadecenoate poly(oxy-1,2-ethanediyl)

derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

9. A formulation according to Claim 4
5 wherein said protein is novel erythropoiesis
stimulating protein (NESP) or a chemically modified
form thereof.

10. A formulation according to Claim 9
10 wherein said NESP has an amino acid sequence as
depicted in SEQ ID NO:2.

11. A formulation according to Claim 10
further comprising a pH buffering agent which provides
15 a pH range of about 5 to about 7.

12. A formulation according to Claim 11
further comprising a stabilizing amount of a sorbitan
mono-9-octadecenoate poly(oxy-1,2-ethanediyl)
20 derivative which is present in a concentration of about
0.001% to 0.1% (w/v).

13. A pharmaceutical multi-dose formulation
comprising a biologically active agent, a preservative,
25 and methionine, wherein said formulation demonstrates
improved stability, and wherein said formulation does
not contain human serum albumin.

14. A formulation according to Claim 13
30 wherein said methionine is present in a concentration
of about 0.5mM to 50mM.

15. A formulation according to Claim 14
wherein said active agent is selected from the group

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consisting of peptides, small molecules, carbohydrates, nucleic acids, lipids, proteins, and analogs thereof.

16. A formulation according to Claim 15
5 wherein said active ingredient is a protein.

17. A formulation according to Claim 16
wherein said protein is erythropoietin (EPO).

10 18. A formulation according to Claim 17
wherein said EPO has an amino acid sequence as depicted
in SEQ ID NO:1.

15 19. A formulation according to Claim 18
wherein said preservative is benzyl alcohol which is
present in a concentration of about 0% to 2% (w/v).

20 20. A formulation according to Claim 19
further comprising a pH buffering agent which provides
a pH range of about 5 to about 7.

25 21. A formulation according to Claim 20
further comprising a stabilizing amount of a sorbitan
mono-9-octadecenoate poly(oxy-1,2-ethanediyl)
derivative which is present in a concentration of about
0.001% to 0.1% (w/v).

30 22. A formulation according to Claim 16
wherein said protein is novel erythropoiesis
stimulating protein (NESP) or a chemically modified
form thereof.

35 23. A formulation according to Claim 22
wherein said NESP has an amino acid sequence as
depicted in SEQ ID NO:2.

24. A formulation according to Claim 23 wherein said preservative is benzyl alcohol which is present in a concentration of about 0% to 2% (w/v).

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25. A formulation according to Claim 24 further comprising a pH buffering agent which provides a pH range of about 5 to about 7.

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26. A formulation according to Claim 25 further comprising a stabilizing amount of a sorbitan mono-9-octadecenoate poly(oxy-1,2-ethanediyl) derivative which is present in a concentration of about 0.001% to 0.1% (w/v).

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27. A method of stabilizing a pharmaceutical composition of a biologically active agent which comprises adding methionine to said composition in amount sufficient to inhibit oxidation of methionine residues in the amino acid sequence of said biologically active agents; wherein said formulation does not contain human serum albumin.

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